



Serpin Pharma was selected for \$1.25 M award by The Virginia Catalyst Fund to conduct COVID-19 Clinical Investigation

Manassas, VA - Serpin Pharma was selected to receive a \$1.25 MM award from The Virginia Catalyst, also known as the Virginia Biosciences Health Research Corporation (VBHRC), for conducting a clinical investigation for the therapeutic role of SP16 drug in mitigating SARS COV2 (COVID-19) progression in hospitalized patients. The Principal Investigator is Serpin Pharma's collaborator, Dr. Michael Yun Shim, John L. Guerrant Associate Professor of Medicine and Medical Imaging, Division of Pulmonary & Critical Care of the University of Virginia.

A key component of COVID-19 disease progression is the activation of innate immune responses in the lungs by viral infection that can lead to a potentially life-threatening, self-perpetual cytokine storm. SP16 is a first-in-class drug that targets LRP1, a critical homeostatic receptor that regulates innate immune mechanisms that contribute to inflammation. Activation of LRP1 by SP16 shuts down principle inflammatory signaling pathways such as NF κ B that effectively curbs cytokine output in favor of anti-inflammatory and healing responses. SP16 also prevents activation of the inflammasome, a driver of innate immune responses activated by a variety of external triggers, including viral infection, that produces cell-death inducing factors, caspase 1, and inflammatory cytokines, IL-1 β and IL-18. A key advantage of SP16 compared to other inflammasome inhibitors that only work to prevent inflammasome assembly, is that SP16 works upstream of the inflammasome, providing complete inhibition of inflammatory cytokines while leaving critical pathways that promote tissue repair in place. The combination of an anti-inflammatory and tissue healing drug is vital, as COVID-19 infection can lead to substantial tissue damage in the lung.

Dr. Cohava Gelber, Chief Executive Officer for Serpin Pharma, said, "SP16 is a potent new anti-inflammatory drug rather than a non-specific, toxic immunosuppressive drug. SP16 reduces the production of inflammatory cytokines (e.g., IL-1 β , TNF- α , IL-6) while sparing normal and protective immune function. SP16 is effective in several animal models of acute inflammation following a severe lung infection. Therefore, SP16, by its ability to inhibit excess cytokine production, may attenuate the development of inflammation-induced lung injury in individuals with COVID-19 infection."

Working with collaborators specializing in infectious diseases, we demonstrated that SP16 significantly inhibited viral replication in COVID-19 infected cells. The dual functionality of the SP16 drug against COVID-19 in mitigating the "cytokine storm" and "out of control" systemic inflammation combined with antiviral activity may afford SP16 drug a potentially higher therapeutic value to COVID 19 patients.

Serpin Pharma is a private, clinical-stage company located in Prince William County's Innovation Park, VA. SP16 is a modified peptide derived from Alpha-1 Antitrypsin (AAT), a Serine Protease Inhibitor (Serpine) that acts as a homeostatic protein and tissue protectant during inflammation. SP16 is a safe drug that regulates innate immune responses (inflammasome) and resolves inflammation by removing harmful surface debris while promoting tissue healing. The company is currently conducting a phase IIa trial in Acute Myocardial Infarction (AMI) patients. SP16 is in development for Eosinophilic Esophagitis (an orphan indication) and Diabetic peripheral neuropathy.